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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/502,176	02/10/00	PIRIE-SHEPHERD	S 05940-0141

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EXAMINER
HARRIS, A

ART UNIT	PAPER NUMBER
1642	11

DATE MAILED: 09/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/502,176

Applicant(s)

PIRIE-SHEPHERD ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 13, 14, 17-26 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15, 16 and 27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/10/2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-12, 15, 16 and 27) in Paper No. 10, filed June 27, 2001 is acknowledged. However, Applicants have not stated the grounds for the traversal. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-28 are pending.

Claims 13, 14, 17-26 and 28 are drawn to non-elected claims.

Claims 1-12, 15, 16 and 27 are examined on the merits.

Priority

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional applications upon which priority is claimed fail to provide adequate support for all of the claims of this application. Provisional applications 60/119,562 (filed February 10, 1999) and 60/128,062 (filed April 7, 1999) do not disclose the use of Kringle 1-5. Hence, priority of the examined claims is the effective filing date of the instant application, February 10, 2000.

Drawings

4. The drawings are objected to because of reasons cited on attached form PTO 948 completed by draftsman. Correction is required.

Specification

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 17, line 20; page 34, line 28 and page 35, line 13. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

6. The disclosure is objected to because of the following informality: the actual figures of figure 1 and the brief description of the figures are not consistent. The figures list SEQ ID NO: 1 as amino acids and SEQ ID NO: 2 as nucleic acid sequences. However, the brief description section on page 8, lines 12 and 13, as well as within the

body of the specification (page 12, line 13 and page 21, line 23) lists the amino acids as SEQ ID NO: 2 and the nucleic acids as SEQ ID NO: 1. Applicants should review the entire specification for similar errors.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-12, 15, 16 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1 and 27 are vague and indefinite in the recitation "fragment of a kringle 1-5 region of a plasminogen". It is not clear as to what kringles should comprise the fragment. Is it all of the kringles, 1-5 or 1-3? As written the metes and bounds of the claim cannot be determined.

b. Claim 1 is vague and indefinite because it is not clear whether or not the composition should comprise just the deglycosylated fragment or both the deglycosylated fragment and the naturally glycosylated form. Accordingly, the metes and bounds of the claim cannot be determined.

c. The recitation "amino acid position Asn-289" in claims 4 and 9 is vague and indefinite because the amino acid sequence of SEQ ID NO: 2 only consists of 260 amino acid residues.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-6, 8, 9, 12, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession number P00747 and Sim et al. (Cancer Research 57:1329-1334, April 1, 1997). Sim discloses a deglycosylated fragment of kringle 1-4 also termed recombinant Angiostatin protein that is approximately kringles 1-3 and begins at approximately amino acid 93, which is within in the range of amino acid 87 (see the Abstract). Fractions of the recombinant Angiostatin were dialyzed and reconstituted in a pharmaceutically acceptable excipient, deionized water (see page 1330, column 1, "Purification of Recombinant..." section). The recombinant protein was digested with endoglycosidase H and O-glycanase with prior neuraminidase treatment to remove carbohydrate moieties (see page 1331, column 2, bridging sentence and first two full sentences). Consistent with this enzyme treatment the deglycosylated fragment inherently lacked a bisialylated-biantennary glycan and a N-linked carbohydrate moiety. As evidenced in the abstract, as well as on pages 1331-1333 the recombinant Angiostatin protein inhibited proliferation of bovine capillary endothelial cells *in vitro* and suppressed the growth of Lewis lung carcinoma-low metastatic (LLC-LM) phenotype metastases in C57BL/6 mice *in vivo*. All sets of data verified that the deglycosylated fragment had antiangiogenic activity both *in vivo* and *in vitro*.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alana M. Harris, Ph.D.
September 5, 2001


SHEELA HUFF
PRIMARY EXAMINER